

GLOBAL HARMONIZATION TASK FORCE

STUDY GROUP 1

FINAL WORKING DRAFT

*Essential Principles of Safety and Performance of
Medical Devices*

This Essential Principles of Safety and Performance of Medical Devices document has been developed to encourage and support global convergence of regulatory systems and the means of achievement. It is intended for use by medical devices regulators, conformity assessment bodies (CABs) and industry, and will provide benefits in establishing, in a consistent way, an economic and effective approach to the control of medical devices in the interest of public health. The document will be of value to countries developing or amending regulations. The regulatory requirements of some countries may not, at present, reflect the contents of this document.

FOREWORD

"Essential Principles of Safety and Performance of Medical Devices on a Global Basis"

Study Group 1 recognizes that to further the processes of global harmonization of regulatory requirements, it is necessary to have common guidelines to indicate the Essential Principles of safety and performance of medical devices in the interests of public health.

Existing regulations and draft regulations of participating members of the Task Force have already included, in many cases, such statements of principles and it has been the conclusion of the Study Group that, although presented in different ways, the features of such principles are common to all such regulations.

For these reasons, Study Group 1 proposes that the following set of principles should be considered in the development or amendment of regulatory systems.

Additionally, the Study Group, having established these Essential Principles, recommends that regulatory agencies consider accepting technical documentation prepared in accordance with these Essential Principles in order to support market entrance of medical devices.

- NOTE: (1) There may be further safety and performance principles for devices incorporating substances derived from tissues of human or animal origin and in vitro diagnostic devices. This may suggest the need for additional review of this Essential Principles document by the Study Group in the future.
- (2) It is understood that the operation of a quality system, the use of standards, post-market vigilance, the pre-market review of a technical file, type testing and final product testing, are all important means, which may individually or jointly be utilized, to achieve compliance with the Essential Principles. These matters are not addressed within this document.
- (3) Information on labelling requirements are the subject of a separate document.

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**ESSENTIAL PRINCIPLES OF SAFETY AND PERFORMANCE
OF MEDICAL DEVICES**

GENERAL REQUIREMENTS

1. Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.
2. The solutions adopted by the manufacturer for the design and construction of the devices should conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer should apply the following principles in the following order:
 - eliminate or reduce risks as far as possible (inherently safe design and construction),
 - where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,
 - inform users of the residual risks due to any shortcomings of the protection measures adopted.
3. The devices should achieve the intended performances, including those claimed by the manufacturer, and be designed, manufactured and packaged in such a way that they are suitable for one or more of the diagnostic or therapeutic functions within the scope of the definition of a medical device applicable in each jurisdiction, as specified by the manufacturer.
4. The characteristics and performances referred to in Clauses 1, 2 and 3 should not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is

subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.

5. The devices should be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.
6. The benefits must be determined to outweigh any undesirable side-effect for the performances intended.

REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION

Chemical, physical and biological properties

- 7.1 The devices should be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Section I on the 'General Requirements'. Particular attention should be paid to:
 - the choice of materials used, particularly as regards toxicity and, where appropriate, flammability,
 - the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device.
- 7.2 The devices should be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention should be paid to the tissues exposed and to the duration and frequency of exposure.
- 7.3 The devices should be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they should be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.
- 7.4 Where a device incorporates, as an integral part, a substance which, if used

separately, may be considered to be a medicinal product/drug as defined in the relevant legislation that applies within that jurisdiction and which is liable to act upon the body with action ancillary to that of the device, the safety, quality and usefulness of the substance should be verified, taking account of the intended purpose of the device.

- 7.5 The devices should be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaching from the device.
- 7.6 Devices should be designed and manufactured in such a way as to reduce, as much as possible, risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used.

Infection and microbial contamination

- 8.1 The devices and manufacturing processes should be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design should allow easy handling and, where necessary, minimize contamination of the device by the patient or vice versa during use.
- 8.2 Tissues of non-human origin as far as considered a medical device, should originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. National regulations may require that the manufacturer and/or the Competent/Regulatory Authority should retain information on the geographical origin of the animals. Processing, preservation, testing and handling of tissues, cells and substances of animal origin should be carried out so as to provide optimal safety security. In particular safety with regard to viruses and other transferable agents should be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.
- 8.3 Devices delivered in a sterile state should be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened.
- 8.4 Devices delivered in a sterile state should have been manufactured and sterilized by an appropriate, validated method.

- 8.5 Devices intended to be sterilized should be manufactured in appropriately controlled (e.g. environmental) conditions.
- 8.6 Packaging systems for non-sterile devices should keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system should be suitable taking account of the method of sterilization indicated by the manufacturer.
- 8.7 The packaging and/or label of the device should distinguish between identical or similar products sold in both sterile and non-sterile condition.

Construction and environmental properties

- 9.1 If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system should be safe and should not impair the specified performances of the devices. Any restrictions on use should be indicated on the label or in the instructions for use.
- 9.2 Devices should be designed and manufactured in such a way as to remove or minimize as far as is possible:
- the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features,
 - risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration,
 - the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given,
 - risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.
- 9.3 Devices should be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention should be paid to devices whose intended use includes exposure to flammable substances or to substances which could cause combustion.

Devices with a measuring function

- 10.1 Devices with a measuring function should be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The limits of accuracy should be indicated by the manufacturer.
- 10.2 The measurement, monitoring and display scale should be designed in line with ergonomic principles, taking account of the intended purpose of the device.
- 10.3 The measurements made by devices with a measuring function should be expressed in legal units as required by the legislation governing such expression of each jurisdiction in which the device is to be sold

Protection against radiation

11.1 General

- 11.1.1 Devices should be designed and manufactured in such a way that exposure of patients, users and other persons to radiation should be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.

11.2 Intended radiation

- 11.2.1 Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it should be possible for the user to control the emissions. Such devices should be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters.
- 11.2.2 Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they should be fitted, where practicable, with visual displays and/or audible warnings of such emissions.

11.3 Unintended radiation

- 11.3.1 Devices should be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of

unintended, stray or scattered radiation is reduced as far as possible.

11.4 Instructions for use

- 11.4.1 The operating instructions for devices emitting radiation should give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.

11.5 Ionizing radiation

- 11.5.1 Devices intended to emit ionizing radiation should be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and energy distribution (or quality) of radiation emitted can be varied and controlled taking into account the intended use.
- 11.5.2 Devices emitting ionizing radiation intended for diagnostic radiology should be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user.
- 11.5.3 Devices emitting ionizing radiation, intended for therapeutic radiology should be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the energy distribution of the radiation beam.

Requirements for medical devices connected to or equipped with an energy source

- 12.1 Devices incorporating electronic programmable systems should be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition (in the system) appropriate means should be adopted to eliminate or reduce as far as possible consequent risks.
- 12.2 Devices where the safety of the patients depends on an internal power supply should be equipped with a means of determining the state of the power supply.
- 12.3 Devices where the safety of the patients depends on an external power supply should include an alarm system to signal any power failure.

- 12.4 Devices intended to monitor one or more clinical parameters of a patient should be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health
- 12.5 Devices should be designed and manufactured in such a way as to minimize the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment.
- 12.6 Protection against electrical risks
 - 12.6.1 Devices should be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed correctly.
- 12.7 Protection against mechanical and thermal risks
 - 12.7.1 Devices should be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance to movement, instability and moving parts.
 - 12.7.2 Devices should be designed and manufactured in such a way as to reduce to the lowest practical level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.
 - 12.7.3 Devices should be designed and manufactured in such a way as to reduce to the lowest feasible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.
 - 12.7.4 Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle should be designed and constructed in such a way as to minimize all possible risks.
 - 12.7.5 Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings should not attain potentially dangerous temperatures under normal use.

12.8 Protection against the risks posed to the patient by energy supplies or substances

- 12.8.1 Devices for supplying the patient with energy or substances should be designed and constructed in such a way that the amount can be set and maintained accurately enough to guarantee the safety of the patient and of the user.
- 12.8.2 Devices should be fitted with the means of preventing and/or indicating any inadequacies in the delivered amount which could pose a danger. Devices should incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.
- 12.8.3 The function of the controls and indicators should be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information should be understandable to the user and, as appropriate, the patient.

Information supplied by the manufacturer

- 13.1 Each device should be accompanied by the information needed to identify the manufacturer, to use it safely and to ensure the intended performance, taking account of the training and knowledge of the potential users. This information comprises the details on the label and the data in the instructions for use, and should be easily understood.

(NOTE: Detailed information on labelling requirements are the subject of a separate document)

Clinical Evaluation

- 14.1 Where conformity with these Essential Principles should be based on clinical evaluation data, such data should be established in accordance with the relevant requirements applicable in each jurisdiction.

Clinical evaluations on human subjects should be carried out in accordance with the Helsinki Declaration adopted by the 18th World Medical Assembly in Helsinki, Finland, in 1964, as last amended by the 41st World Medical Assembly in Hong Kong in 1989. It is mandatory that all measures relating to the protection of human subjects are carried out in the spirit of the Helsinki Declaration. This

includes every step in the clinical investigation from first consideration of the need and justification of the study to publication of the results. In addition, some countries may have specific regulatory requirements for pre-study protocol review or informed consent.

(NOTE: Specific guidance on clinical evaluation may be developed by Study Group 1 in the future)